Message

From: Johnson, Hope [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3B09505742524543 93A8915C2F21A711-HOPE JOHNSON]
Sent: 3/17/2016 4:21:47 PM
To: danielle.larochelle@us.nufarm.com
CC: Manupella, Matthew [Manupella.Matthew@epa.gov]
Subject: RE: Calcium Oxytetracycline Technical_Acute toxicity data requirements

That is an argument you could try to make for your application with either a citation or waiver request for those required studies. Nothing will be reviewed prior to submission of your application. If your argument is not acceptable, you could receive a 10 day deficiency letter for the application.

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: danielle.larochelle@us.nufarm.com [mailto:danielle.larochelle@us.nufarm.com]
Sent: Thursday, March 17, 2016 11:38 AM
To: Johnson, Hope <Johnson.Hope@epa.gov>
Cc: Manupella, Matthew <Manupella.Matthew@epa.gov>
Subject: RE: Calcium Oxytetracycline Technical_Acute toxicity data requirements

Matt and Hope - Thanks for your prompt response.

Hope,

As I mentioned to Matt, we are considering registering a new calcium oxytetracycline technical product (about 90% purity). I would greatly appreciate it if you could verify whether the information below would apply to a new oxytetracycline technical product.

According to the following information from 1) the HED Scoping Document for the Registration Review, 2) the Oxytetracycline TRED, and 3) the Oxytetracycline HED Chapter of the TRED, it appears that the acute toxicity data requirements may be waived for a "high purity" calcium oxytetracycline technical product (90%).

HED Scoping Document for the Registration Review (page 2 of 14)

"According to the TRED, the toxicology database for oxytetracycline is complete and a new literature search for this scoping document has produced no new toxicology studies that warrant reconsidering any of the toxicology decisions in the TRED"

Oxytetracycline TRED (page 4 of 15, first paragraph under Use Profile)

"In this document, unless specified otherwise, "oxytetracycline" refers to both oxytetracycline hydrochloride and oxytetracycline calcium; there is no active product for PC Code 006304."

Oxytetracycline TRED (page 7 of 15, 3rd paragraph)

Oxytetracycline has a low acute toxicity (Category IV) for oral toxicity in mice (LD_{50} > 7200 mg/kg). Based on the availability of extensive information from oxytetracycline use as a human drug, the data requirements for the acute dermal, inhalation, primary eye irritation, and skin sensitization studies in animals have been waived.

Oxytetracycline: HED Chapter of the TRED and Proposed New Uses on Apples. (Revised After Phase 3 Public Comment Period) Dated 19-JUN-2006
(page 43 of 46) (attached)

11.0 APPENDICIES

1.0 TOXICOLOGY DATA REQUIREMENTS

The requirements (40 CFR 158.340) for food uses of oxytetracycline are listed in the table below. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used. The prenatal developmental and carcinogenicity studies in rodents are the only acceptable submitted studies in the oxytetracycline database. Historically, all database requirements were waived based on animal data that are available from various sources (open literature, NTP, etc). Thus, the agency did not require any toxicity studies on the technical grade ingredient. This waiver is justified based on the current availability of animal data. Therefore, none of the studies are required but all of the study requirements are satisfied by the plethora of information available on oxytetracycline in animals. The data obtained from various sources are listed in Tables 4.1a and 4.1b.

Test	Technical	
	Required	Satisfied
870.1100 Acute Oral Toxicity	Yes	yes
870.1200 Acute Dermal Toxicity	Yes	waived
870.1300 Acute Inhalation Toxicity	No	--
870.2400 Primary Eye Irritation	No	--
870.2500 Primary Dermal Irritation	No	--
870.2600 Dermal Sensitization	No	--

I really appreciate any help you can provide to clarify the acute toxicity data requirements for a new calcium oxytetracycline technical product (about 90% purity).

Many thanks.

Danielle

Danielle A. Larochelle | Regulatory Manager
Nufarm Americas Inc. | 4020 Aerial Center Parkway, Suite 101, Morrisville, NC 27560 | USA
T: (919) 379-2530 | M: (919) 500-0925 | e: danielle.larochelle@us.nufarm.com

From: "Johnson, Hope" <Johnson.Hope@epa.gov>
To: "Manupella, Matthew" <Manupella.Matthew@epa.gov>, "danielle.larochelle@us.nufarm.com" <danielle.larochelle@us.nufarm.com>,
Date: 03/17/2016 09:06 AM
Subject: RE: Calcium Oxytetracycline Technical_Acute toxicity data requirements

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Acute toxicity data must be submitted or cited for any new product, and the acceptability of is determined by our Acute Toxicology

group. Refer to 158.500 requirements in the CFR- guidelines 870.1100-.2600

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

From: Manupella, Matthew
Sent: Thursday, March 17, 2016 8:59 AM
To: danielle.larochelle@us.nufarm.com
Cc: Johnson, Hope <Johnson.Hope@epa.gov>
Subject: RE: Calcium Oxytetracycline Technical_Acute toxicity data requirements

Hi Danielle,

That would be a better question for RD. I'm sure Hope can help you.

Thanks,
Matt

From: danielle.larochelle@us.nufarm.com [mailto:danielle.larochelle@us.nufarm.com]
Sent: Wednesday, March 16, 2016 5:26 PM
To: Manupella, Matthew <Manupella.Matthew@epa.gov>
Subject: Calcium Oxytetracycline Technical_Acute toxicity data requirements

Hi Matt,

We are considering registering a new source of calcium oxytetracycline for the technical product (55146-99). The HED Chapter for the Oxytetracycline TRED states on page 43 that the Agency does not require "any toxicity studies on the technical grade ingredient" (see attachment). I wanted to make sure that this applies to Calcium Oxytetracycline Technical - can you confirm?

Thank you very much!

Danielle

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